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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,919	02/22/2002	Lucia Irene Gonzalez-Villasenor	22918/1	7790
7590	07/14/2004		EXAMINER	
Thomas M Saunders Brown Rudnick Berlack Israels LLP 18th Floor One Financial Center Boston, MA 02111			MONDESI, ROBERT B	
			ART UNIT	PAPER NUMBER
			1653	
			DATE MAILED: 07/14/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,919	GONZALEZ-VILLASENOR, LUCIA IRENE	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This office action is in response to the amendment filed May 10, 2004. **Claims 1-47** as drawn to elected Invention I are currently pending and are under examination.

Withdrawal of Objections and Rejections

The objection of specification because of an informality is withdrawn.

The rejection of **claims 1-16, 20, 22-24, 26-44 and 46-47** under 35 U.S.C § 112, second paragraph is withdrawn.

The rejection of **claims 17-19** under 35 U.S.C § 102(b) as being anticipated by Moses is withdrawn.

The rejection of **claims 1-6, 15 and 43** under 35 U.S.C § 103(a) as being unpatentable over Mahmoud et al. in view of Dorin et al. is withdrawn.

The rejection of **claim 16** under 35 U.S.C § 103(a) as being unpatentable over Mahmoud et al. in view of Dorin et al. and liu is withdrawn.

The rejection of **claims 26-32, 38-39 and 41-42** under 35 U.S.C § 103(a) as being unpatentable over Dorin et al.; Darling; Couch and Schein is withdrawn.

The rejection of **claims 33-37** under 35 U.S.C. 103(a) as being unpatentable over Dorin et al. as applied to **claim 26**, and further in view of Darling et al.; Couche et al and Schein is withdrawn.

The rejection of **claims 44- 47** under 35 U.S.C. 103(a) as being unpatentable over Olson et al. in view of Schein et al. is withdrawn.

Maintenance of rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. Lee et al. disclose the product Troponin ; and a method comprising dialyzing and ultrafiltering a polypeptide into an aqueous buffer that is denaturant-free wherein the polypeptide is Troponin (column 10 lines 32-39). Lee et al. also teach that the dialyzed samples containing Troponin are dispensed into vials or tubes (column 10, lines 38-40) (**Present claims 20-21**). Thus, Lee et al. teach all the elements of **claims 17-19** and these claims are anticipated under 35 USC 102(b).

Response to applicant's arguments

In section VII.C the applicant asserts that:

- A. The purified protein of Lee et al. is from a natural source and not a recombinant protein.
- B. The method disclosed in Lee et al. is unrelated to the applicant's invention within claims 20-21, in which crude or purified bioactive polypeptide can be either dialyzed or

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ultrafiltered against a low salt buffer with stabilizers and without reducing agent, because the polypeptide in the applicant's claimed invention is already bioactive.

C. The material produced by the method of Lee et al. can not be used in animal or human studies as it has no biological activity.

In response to the applicant's assertions the examiner would like to point out that the fact that the applicant's method involves a recombinant protein has not been stated in the claims nor do the claims state that the material produced by the applicant's method is used in animal or human studies. Applicant's arguments are not found persuasive because limitations that are in the specification but not in the claims are not given patentable weight. Even if the claims recited the use of the protein in animal or human studies, it would not be given patentable weight in a composition claim because it would be merely a statement of intended utility.

In regards to term "bioactive" the applicant's attention is directed to the NEW REJECTIONS section of the present office action.

In section IX the applicant asserts that:

The cited reference Schein, does not teach any particular concentration in which a crude solubilized protein is stabilized during the process of solubilization of refractile bodies containing minute amounts of polyol and sugar and in the presence of low sodium hydroxide concentration to produce a bioactive polypeptide as the applicant has disclosed and claims.

Again In regards to the phrase "a bioactive polypeptide" the applicant's attention is directed to the NEW REJECTIONS section of the present office action.

New rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In **claims 1-47** the applicant recites a bioactive polypeptide that has been isolated using the method of the invention. However the applicant has not shown to a person of skill in the art that he/she had possession of the invention at the time of filing of the present application. In order to show to a person skill in the art that the polypeptide isolated using the method of the invention has activity or is "bioactive", the applicant would need to provide a biological assay that demonstrates the activity of the said isolated polypeptide. On page 16 (lines 1-6) the applicant states that biological activity is determinable *in vitro* or *in vivo* by carrying out suitable bioassays to determine the potency or activity of protein preparations (page 16, lines 1-5). In view of the applicant's definition, Orsini et al. demonstrate that the

bioactive polypeptide isolated using their method has retained its activity. On page 693, Orisin et al. perform a Fibrin clot-lysis experiment wherein fibrinolytic activity of proUK and 125-proUK was evaluated by an in-vitro clot lysis test (data shown in table 1, page 693). Without such data it would not be possible to show to person skill in the art that the applicant had possession of the method of the invention at the time of filling of the present application.

In **claims 1-47** the applicants cite a method of solubilizing and recovering a target polypeptide. However, an important section of the specification, designated as example 7, that provides support and written description for the method of the invention is presently not included in the specification. The applicant has made a multitude of references to this seemingly important example (page 45, lines 9-11, 21; page 46, lines 4-5, 15-16, lines 23-24). Without this important section (example 7) it would not be possible to show to a person skill in the art that the applicants had possession of the invention at the time of filing of the present application.

Claims 21-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "target protein" in line 1. There is insufficient antecedent basis for this limitation in the claim

Claim 22 recites the limitation "stabilization solution" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 23-25 recites the limitation "the formulation solution" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim

Conclusion

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RB Mon

Robert B. Mondesi
Patent Examiner
Group 1653
07-08-04



ROBERT A. WAX
PRIMARY EXAMINER